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ब्रिक–ट्रांसलेशनल स्वास्थ्य विज्ञान और प्रौद्योगिकी संस्थान
BRIC a DBT Organization
BRIC-Translational Health Science and Technology Institute
(An Institute of the Biotechnology Research and Innovation Council, Govt. of India)
NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurugram Expressway,
P.O. Box No. 04, Faridabad – 121001

Recruitment notice no.: THS-C/RN/19/2024 **Dated: 02 September 2024**

1. BRIC-Translational Health Science and Technology Institute (THSTI) is an Institute of the Biotechnology Research and Innovation Council, Department of Biotechnology, Ministry of Science & Technology, Govt. of India. The institute is an integral part of the interdisciplinary NCR Biotech Science Cluster located at Faridabad, and is designed as a dynamic, interactive organization with the mission to conduct innovative translational research and to develop research collaborations across disciplines and professions to translate concepts into products to improve human health.

2. BRIC-THSTI has built several inter-institutional collaborations and connectivity with industry supported by well-trained teams of research and laboratory staff. THSTI has established various centres namely (a) Centre for Maternal and Child Health, (b) Centre for Viral Therapeutics and Vaccines (c) Centre for Tuberculosis Research (d) Centre for Microbial Research, (e) Centre for Immunobiology and Immunotherapy (f) Centre for Drug Discovery (g) Clinical Development Services Agency (h) Computational and Mathematical Biology Centre (i) Centre for Bio-design and Diagnostics. These centres are strengthened by many core facilities viz. Bioassay Laboratory, Biorepository, Biosafety Level -3 Lab, Data Management Centre, Immunology Core laboratory, Multi-OMICS facility, Experimental Animal Facility, Vaccine design and Development facility, School of Innvoation in Biodesign etc that serve as huge resources for the research programmes of THSTI and also the National Capital Region Biotech Science Cluster and other academic and industrial partners.

3. This recruitment is to fill up the vacancies for project positions at Clinical Development Services Agency (CDSA) center. CDSA is a niche center of THSTI established to facilitate development of affordable healthcare products for public health diseases. It is the only public Centre in the country created with a mandate to support and nurture cost-effective, high quality, not-for-profit technology-based preclinical and clinical product developmentas well as support clinical research conducted by public agencies. It works towards development of an eco-system for training and learning and work with public sector institutions, and small and medium enterprises (SME) to translate innovative technologies into medical products for public good.

   The main objectives of CDSA are:

   a) As an academic Clinical Research Unit, to undertake & provide end -to- end clinical study support for investigators and SMEs in study planning, set up, conduct: project management, monitoring, data management, safety reporting, analysis and report writing
   b) Build research capacity and capability through high quality training in the area of clinical development/trials and regulation
   c) Support and strengthen clinical research environment in the country
   d) Regulatory science and policy support: provide tools and approaches to support researchers, regulators, health policy makers & industry

Applications are invited from eligible candidates to fill up the following positions:

1.	**Name of the post**	Program Manager (Equivalent to Project Research Scientist-II) (Non-Medical)
	Name of the project	ICMR - AI
	Number of posts	01
	Emoluments	Rs. 67,000/- + 18% HRA = Rs. 79,060/-
	Age	Up to 40 years
	Duration	Up to March 2025 (Can be extend further)
	Minimum Educational Qualification and Experience	**Essential qualification and work experience:** • MBBS with minimum two (2) years of experience in clinical project management and/or clinical trial/ study monitoring. **OR** • BDS / Allied Medical Degree with minimum three (3) years of experience in clinical project management and/or clinical trial/ study monitoring. **OR** • Master's Degree / PG Diploma in Life Sciences / Biomedical Sciences / Pharmacy / Public Health / Clinical Research with minimum five (5) years of experience in clinical project management and/or clinical trial/ study monitoring. **AND** • Experience in clinical trial or public health project management in a recognized organization/institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or medical device company) **Desirable qualification and work experience:** • Postgraduate degree in Public Health • MD/DNB from a recognized Indian University/ recognized by MCI • PhD in a health-related discipline • Demonstrable experience of line management, project management concepts and ability to understand, explain and communicate project concepts using standard tools and templates.
	Job Profile	The position is responsible for Responsible for oversight, management and operational execution of assigned clinical studies and trials. Timely delivery of key tasks, while maintaining high quality standards are: - • The project manager will manage the performance of project team working on projects. • The Project Manager must ensure the integrity of the trial by monitoring data, processes, and documentation both onsite and remotely. • Conducting site qualification, initiation, monitoring, and close-out visits for designated clinical trial and willing to travel to all clinical sites across India on short notice, and stay for extended periods as required. • The management and cross-functional coordination of the project and work closely to develop and maintain the overall project plan

		and timelines, communicate project expectations to the respective resource/consultant and manage the overall project budget. • Support the team in the implementation of systems for resource planning, study / trial administration, implementation, oversight monitoring, quality assurance and documentation and record keeping under the supervision of Chief-CPM. • Establishment of procedures to ensure adherence to trial protocols and administrative requirements. • Develop project specific and protocol specific training or as requested. • Monitoring the trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems • Understand the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and coordinating any necessary audit processes • Liaison with Steering Committee and DSMB with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirement • Work with the Investigators to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding, or timelines • Development, approval, and distribution of study-related documents including Case Report Forms (CRF's), study protocols, study manuals, and other study tools to investigational sites and review committees • Manage distribution, collection and tracking of regulatory documentation to ensure compliance with regulatory and project requirements and audit readiness • Work with data management and other departments to track progress, milestones and the challenges • Communicate to team members the scope of work, timeline and project goals, technical information or update. • Provide guidance and operational area training for project team members and staff as required • Faculty for training projects conducted by CDSA • Any other assignment with Clinical Portfolio Management team, based on project deliverable or exigencies.
	Skills	• Leadership skills that include the ability to build effective project teams, ability to motivate others, delegation, drive and timely/quality decision making • Personal qualities that include the ability to gain trust and confidence with a variety of clients, good learning ability, managerial courage, action oriented and resilience in a fast- paced and rapidly changing environment • Comprehensive understanding of Indian Clinical Trials Regulations, ICH and CDSCO Good Clinical Practice • Business/ Operational skills that include commitment to quality management and problem solving • Influencing skills including negotiation and teamwork

2.	**Name of the post**	Quality Manager (Equivalent to Project Research Scientist-I) (Non-Medical)
	Name of the Project	ICMR_AI
	Number of posts	01
	Emoluments	Rs. 56,000/- + (18% HRA) = Rs. 66,080/-
	Age	Up to 35 years
	Duration	Up to March 2025 (Can be extend further)
	Minimum Educational Qualification and Experience	**Essential qualification:** • Master's Degree or PG Diploma in Life Sciences or Biomedical Sciences or Pharmacy or Public Health or Clinical Research. • At least 4 years of demonstrated experience in clinical trial monitoring or clinical site management experience. • GCP Certification. **Desirable work experience:** • GCLP Certification or experience of monitoring of laboratory-based activities/ research. • Two years of work experience in the area of Quality Control and Quality Assurance in clinical research.
	Job profile	• The Quality Manager is responsible for the oversight, management and operational execution of assigned clinical studies and trials under the supervision of the Project Manager and the Chief-CPM. • The Quality Manager must ensure the integrity of the trial by monitoring data, processes, and documentation both onsite and remotely. • Ensure high-quality standards on delivery of key tasks with adherence to project timelines and deliverables. • Conducting site qualification, initiation, monitoring, and close-out visits for designated clinical trial and willing to travel to all clinical sites across India on short notice, and stay for extended periods as required. • Understand the requirements and frameworks of the various regulatory bodies such as DBT, ICMR, HMSC etc, and guide the project conforming to those requirements. • Responsible for the establishment of quality assurance procedures and time points across various aspects of the overall project functioning. • Prepare a risk assessment and mitigation plan for the study and, ensure its implementation. • Establishment of procedures to ensure adherence to trial protocols and administrative requirements. • Develop project specific and protocol specific training or as requested. • Monitoring the trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems. • Work with the Investigators to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding, or timelines. • Development, approval, and distribution of study-related documents

		including Case Report Forms (CRF's), study protocols, study manuals, and other study tools to investigational sites and review committees. • Work with data management and other departments to track progress, milestones and the challenges. • Communicate to team members the scope of work, timeline and project goals, technical information or update. • Provide guidance and operational area training for project team members and staff as required • Responsible for the training, task allocation and evaluation of the performance of the study monitors. • Any other assignments with the Clinical Portfolio Management team, based on project deliverable or exigencies.
	Skills	• Ability to work independently with minimal guidance as well as collaboratively within a team setting. • Leadership skills that include the ability to build effective project teams, ability to motivate others, delegate, drive and timely/quality decision-making • Business/ Operational skills that include a commitment to quality management and problem-solving. • Effective communication skills that ensure the provision of timely and accurate information to stakeholders. Proficient in English, Strong written and oral communication skills. • Proficient in computer literacy in Excel, Word, PowerPoint, and Access. • Good writing skills, including the ability to develop and deliver presentations, prepare technical reports, manuscripts, monitoring plans and SOPs. • Comprehensive understanding of Indian Clinical Trials Regulations, ICH and CDSCO Good Clinical Practice • Knowledge of regulations and guidelines pertaining to the conduct of clinical trials/ studies on human subjects. • Personal qualities that include the ability to gain trust and confidence with a variety of clients, good learning ability, managerial courage, ability to prioritize workload, action-oriented and flexible to accommodate in changing environment. • Influencing skills including negotiation and teamwork.
3	**Name of the post**	Project Associate (Equivalent to Project Technician -III)
	Number of posts	02
	Name of the Project	ICMR_AI
	Emoluments	Rs.28000 + 18 % HRA = Rs. 33,040/-
	Age	35 Years
	Duration	Up to March 2025 (Can be extend further)
	Minimum Educational Qualification and Experience	**Essential qualification:** • Bachelors in Life Sciences with minimum two (2) years of relevant research experience. **OR** • Master's degree/ diploma, life sciences, pharmacy, public health, healthcare or other related discipline with minimum one (1) year of

		relevant research experience.
	Job Profile	• Reviews and develops a familiarity with the protocol, e.g., study proceedings and timelines, inclusion and exclusion criteria, confidentiality, privacy protections. • Performs data monitoring, process monitoring and ensures the maintenance of the essential documents at the trial sites and CDSA. • Support on-site co-monitoring visits with PM and QM and willing to travel across all the trial site on a need basis. • Assists study team in communication of study requirements to all individuals involved in the study. Provides appropriate training and tools for study team members. Documents date of training and signatures of study personnel trained on study specific training log. • Responsible for supporting clinical study documents development for start-up activities and other study documents/dossiers as per project requirement and assist in collation and preparation of clinical study documents for submission for regulatory and EC approvals. • Supports creation, maintenance and periodic review of Trial Master Files, Tools and Systems for accuracy and completeness as per the regulatory and GCP requirements. • Participate in project related meetings and assist in preparation of agendas, presentation materials, minutes, and tracking of action items. • Assist project team in the preparation, handling, distribution, filing, and archiving of clinical study documentation as per departmental SOPs and project requirements. • Work with Clinical Portfolio Management and other internal departments on their requirements as and when require.
	skills	• Strong communication skills both verbal and written in English. • Proficient in Microsoft Office, including Word, Excel, PowerPoint, Outlook etc. and working experience with project management software. • Ability to work under pressure, exhibit integrity in behavior and action. • Ability to remain flexible and work independently with minimal guidance as well as collaboratively within a team setting.
➢Last date of receipt of online application: **22nd September 2024.** ➢The application will be scrutinized/shortlisted and processed for further selection.		

SUBMISSION OF APPLICATION WILL BE THRU ONLINE MODE ONLY OTHERWISE IT WILL GET REJECTED OR IGNORED.

GENERAL TERMS & CONDITIONS: -

a) This is short-term positions and extension will be granted subject to satisfactory performance of the incumbents and tenure of the project for which they are selected. Those appointed to these positions will not have any claim for regularization of their employment.

b) All educational, professional and technical qualification should be from a recognized Board/University.

c) The experience requirement specified above shall be the experience acquired after obtaining the minimum educational qualifications specified for the post.

d) Closing date of online application will be the **CRUCIAL DATE** for determining eligibility with regard to age, essential qualification etc.

e) Number of positions to be hired, age limit, qualification, experience and other requirements may be relaxed at the discretion of the competent authority, in case of candidates who are otherwise suitable. In case candidates are not found suitable for the postsnotified, they can be offered lower post / lower emoluments on the recommendation of the Selection Committee.

f) Age and other relaxations for direct recruits and departmental candidates: 1. By five years for candidates belonging to SC/ST communities. 2. By three years for candidates belonging to OBC communities. 3. For Persons with Benchmark Disabilities (PWBD) falling under the following categories: (i) UR - ten years, ii) OBC - 13 years (iii) SC/ST - 15 4. Age is relaxable for Central Government servants up to five years in accordance with the instructions or orders issued by the Central Government, from time-to-time. 5. There is no upper age limit for the Institute employees who are treated as departmental candidates.

g) All results will be published on our website and all future communications will be only through email

h) In case a large number of applications are received, screening will be done to limit the numberof candidates to those possessing higher/relevant qualification and experience.

i) With regard to any provisions not covered in this notification, the bye laws of THSTI / Govt. of India rules / guidelines shall prevail.

j) Canvassing wrong in any form will be a disqualification.

k) The candidate may be transfer to site location as per the project requirement and management discretion.

HOW TO APPLY:

1. **Documents to be kept handy before filling up the online application:** (all the documents except (i) should be in pdf format):

   i) A soft copy of your passport size photo and signature. (jpeg/jpg/png format)
   ii) A comprehensive CV containing details of qualification, positions held, professional experience / distinctions etc.
   iii) Matriculation certificate (equivalent to 10th Standard) / Mark sheet
   iv) Intermediate certificate (equivalent to 12th Standard) / Mark sheet
   v) Graduation/Diploma degree certificate / Mark sheet
   vi) Post-Graduation degree certificate & Mark sheet (if applicable)
   vii) PhD/MD Degree (if applicable)
   viii) Relevant experience certificates (if applicable)
   ix) Caste / Disability certificate in the format prescribed by the Govt. of India, if applicable.
   x) Forwarding letter / NOC from the current employer in the case of candidates working in Govt. / PSUs / autonomous bodies.

2. **Procedure for filling up online application:**

   i) The eligible and interested candidates may apply online at the Institute's website https://thsti.res.in/en/Jobs. Applications through any other mode will not be accepted.

ii) The following will be the step wise procedure-

A) Step 1 : Details of applicant

B) Step 2 : Uploading of documents

C) Step 3 : Payment of application fee

- The payment can be made by using Debit Card / Credit Card / Internet Banking / UPI.
- Once payment is made, no correction / modification is possible
- Candidates are requested to keep a copy of the provisional receipt for future reference.
- Fee once paid shall not be refunded under any circumstances.
- Details of fees to be paid are as shown below:

S. No.	Applying on direct recruitment	Applicationfee amount
1.	Unreserved, OBC & EWS candidates	Rs. 590/-
2.	SC/ST/Women/PwBD	Rs 118/-

D) Step 4 : Submission of application form.

iii) On successful submission of application, an auto-generated email containing the reference number will be sent to the email address provided. Please keep a note of the reference number for future correspondence.

iv) Candidates are required to keep a printout of the online application form by using the print button on the dashboard for future reference.

v) Candidates must ensure that he / she fulfils all the eligibility criteria as stipulated in the advertisement. If it is found that he / she does not fulfil the stipulated criteria during the recruitment process, the candidature of the candidate will be cancelled. If the same is noticed after the appointment, the candidate will be terminated following due process.

vi) Incomplete applications shall be summarily rejected and no correspondence in this regard shall be entertained.

vii) In case of difficulty in filling up the online form, please send e-mail to **HR.CDSA@THSTI.RES.IN** along with the screenshot of the error displayed (if any).

"Government strives to have a work force which reflects gender balance and women candidates are encouraged to apply"

(M.V.Santo)
Head-Administration

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